

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Thomas J. FOGARTY, et al.

Application No.: 10/646,639

Filed: August 22, 2003

For: **PROSTHESIS FIXTURING DEVICE AND  
METHODS OF USING THE SAME**

Confirmation No.: 9788

Art Unit: 3774

Examiner: PREBILIC, Paul B.

Atty. Docket: P0038129.00  
(1737.3740000)

**Brief on Appeal to the Board of Patent Appeals  
And Interferences Under 37 C.F.R § 41.37**

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Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

On January 25, 2010, Appellants filed a Notice of Appeal from the decision of the Examiner set forth in the final Office Action mailed July 24, 2009 ("the final Office Action"), entering a final rejection of claims 1-2, 9-10, 16, 21, 29-32, 34, 37, 41, 51-53, 56, 74, 96, 113-114, and 116-130 in the above-captioned U.S. Patent Application.

Appellants file this Brief on Appeal under 37 C.F.R. § 41.37(a)(1), together with the required fee under 37 C.F.R. § 41.20(b)(2), in support of the Appeal.

It is believed that no extensions of time or fees are required beyond those that may otherwise be provided for in the documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

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***I. Real Party in Interest (37 C.F.R. § 41.37(c)(1)(i))***

The real party of interest in this Appeal is Medtronic, Inc, having its principal place of business at 710 Medtronic Parkway, Fridley, Minnesota 55432. An assignment assigning all right, title, and interest in and to the patent application from FOGARTY, Thomas J.; DREWS, Michael J.; LANE, Ernest; HOLMGREN, Neil; and GUTIERREZ, Federico ("the inventors") to Arbor Surgical Technologies, Inc., was recorded in the U.S. Patent & Trademark Office on January 15, 2004, at Reel 014264, Frame 0820. An assignment assigning all right, title, and interest in and to the patent application from Arbor Surgical Technologies, Inc., to Medtronic, Inc., ("Assignee") was recorded in the U.S. Patent & Trademark Office on February 5, 2010, at Reel 023928, Frame 0383.

***II. Related Appeals and Interferences (37 C.F.R. § 41.37(c)(1)(ii))***

To the best of knowledge of Appellants, Appellants' legal representative, and the Assignee, there are no other prior or pending appeals, interferences, or judicial proceedings which may be related to, will directly affect, or may be directly affected by or have a bearing on a decision by the Board in the present pending Appeal.

***III. Status of the Claims (37 C.F.R. § 41.37(c)(1)(iii))***

This application was originally filed as U.S. Application No. 10/646,639 on August 22, 2003, with ninety-one (91) claims. Original claims 1, 66, 74-76, 83, and 90-91 were the original independent claims.

In an initial Office Action mailed March 22, 2006, the Examiner presented a restriction requirement. Specifically, the Examiner required restriction to: I. Claims 1-75, drawn to the device; and II. Claims 76-91, drawn to a method of use. The Examiner also required election of species. First, the Examiner required an election of one figure from Species Set 1, which included Figures 4-75, for prosecution. Second, the Examiner required election of one set of figures from Species Set 2, which included seventeen sets of figures that the Examiner asserted were directed to gaskets. In an Amendment and Response to the Restriction/Election requirement filed May 22, 2006, Appellants elected Group 1 in response to the restriction requirement. Appellants also elected Figures 49 and 50 from Species Set 1, and Figure 25 from Species Set 2. Appellants cancelled claims 6-8, 66-73, and 76-91, and added new claims 92-118 in the Amendment and Response.

In an Office Action mailed August 2, 2006, the Examiner rejected claims 1-2, 9-10, 14-21, 24, 29-31, 34, 41, 51-54, 56, 74, 92-95, 97-112, and 114-115. The Examiner objected to claims 51-53, 74, 93, and 98-100 as being unclear because the preamble recited "a device for connecting a heart valve to a first mass," but the bodies of the objected to claims positively recited the heart valve, allegedly making it unclear if the heart valve was positively recited. The Examiner also objected to the drawings, stating that Figures 1-3 should be designated as --Prior Art-- because only that which is old is illustrated. The Examiner also objected to the specification as failing to provide proper antecedent basis for the terms shelf and slope in claims 92, 107, 109, 115, and 117. The Examiner indicated that claims 32, 37-

39, 96, 113, and 116-118 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims. In an Amendment and Response filed on January 3, 2007, Appellants amended the specification and the drawings, cancelled claims 17-20 and 75, amended claims 1, 21, 74, 92, 98-100, 108, and 15, and rewrote claims 32, 37, 96, 113, and 116-117 in independent form.

On March 30, 2007, the Examiner issued a Notice of Non-Compliant Amendment, stating that claims 42 and 44 were missing from the claim set presented on January 3, 2007. Appellants filed a corrected claim set on April 16, 2007.

In an Office Action mailed June 19, 2007, the Examiner rejected claims 1-5, 9-10, 16, 21, 29-32, 34-39, 41-44, 46-57, 64, 74, 92-109, and 111-118. The Examiner indicated that claims 92-95, 97-109, 111-112, and 115 had been withdrawn as drawn to a non-elected invention. The Examiner objected to Figures 26-27 and 1-3. The Examiner objected to claims 1, 32, and 37 due to informalities. In an Amendment and Response filed on November 19, 2007, Appellants submitted replacement drawings, cancelled claims 38-39, 92-95, 108-109, 111-112, and 115, amended claims 1, 29, 32, 37, 74, 97-98, 101-102, and 106-107, and added new claims 119-130.

In a non-final Office Action dated August 19, 2008, the Examiner rejected claims 1-2, 9-10, 16, 21, 29-32, 34, 37, 41, 51-54, 56, 74, 96, 113-114, and 116-130. In an Amendment and Response filed on December 19, 2008, Appellants cancelled claims 54, 57, and 64, and amended claims 1, 32, 37, 48, 55-56, 74, 96, 113, 116-117, 119, and 125.

In a non-final Office Action dated July 24, 2009, the Examiner rejected claims 1-2, 9-10, 16, 21, 29-32, 34, 37, 41, 51-53, 56, 74, 96, 113-114, and 116-130.

This Appeal is taken from the final rejection of claims 1-2, 9-10, 16, 21, 29-32, 34, 37, 41, 51-53, 56, 74, 96, 113-114, and 116-130 set forth in the Final Office Action

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Accordingly, the claims on appeal are claims 10-12, 15-17, 27, 32, and 35-59. A copy of the claims on appeal can be found in the CLAIMS APPENDIX, included herein as Section IX, as required under 37 C.F.R. § 41.37(c)(1)(viii).

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***IV. Status of Amendments (37 C.F.R. § 41.37(c)(1)(iv))***

All amendments have been entered. No additional amendments were filed after issuance of the July 24, 2009, final Office Action.

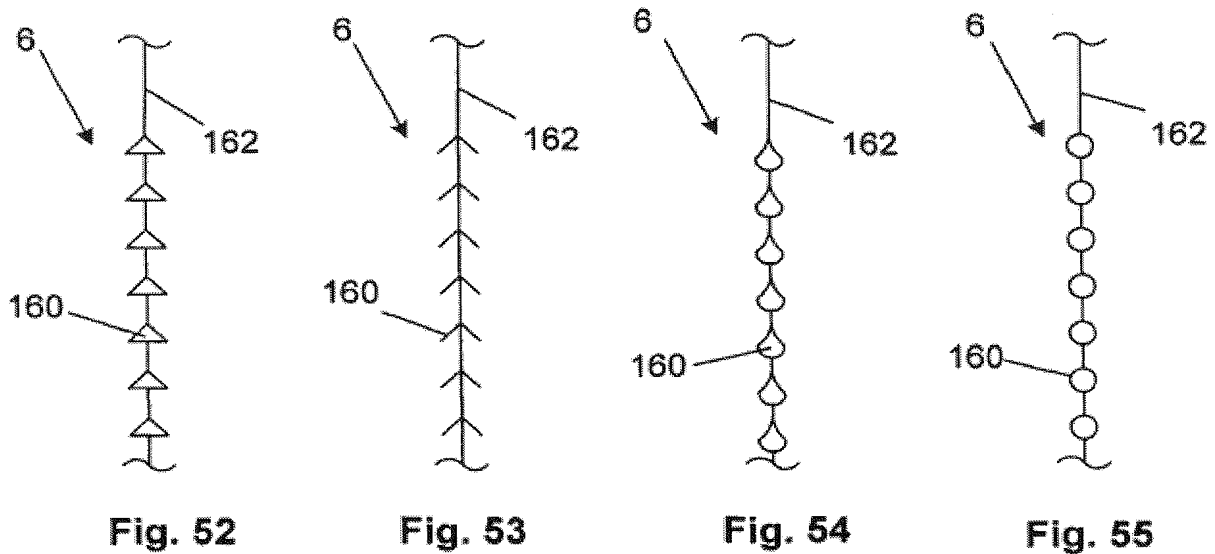
***V. Summary of Claimed Subject Matter (37 C.F.R. § 41.37(c)(1)(v))***

**Subject matter common to all claims on Appeal**

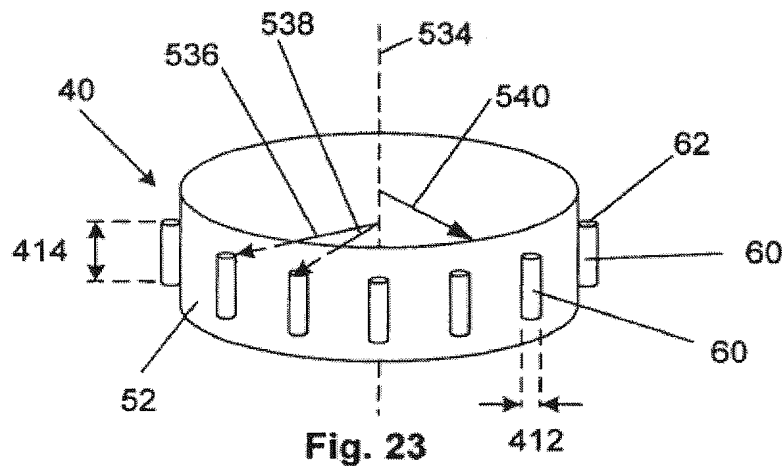
The claimed subject matter relates to devices for fixturing a prosthesis to a first mass and methods of making and using the same. Specification as filed, p. 1, ll. 14-15; p. 4, l. 22 - p. 6, l. 18. The fixturing devices disclosed in the application are intended to minimize the time required to fix a valve prosthesis to a first mass, which can be surrounding tissue or a second prosthesis. Specification as filed, p. 4, ll. 11-13.

The specification explains that, in typical prosthetic valve implantation procedures, a patient's aorta is incised and the defective valve is removed. Specification, p. 1, ll. 21-23. Sutures can then be passed through the fibrous tissue or desired placement site within the valve annulus to form an array of sutures. Specification as filed, p. 1, l. 23 - p. 2, l. 2. Free ends of the sutures are extended out of the thoracic cavity and laid, spaced apart, on the patient's body. Specification as filed, p. 2, ll. 2-3. The free ends of the sutures are then individually threaded through a flange of the sewing ring of a prosthesis while the prosthesis is outside the patient's body. Specification as filed, p. 2, ll. 3-4. Once all the sutures have been passed through the sewing ring, all the sutures are pulled taught and the prosthetic valve is slid or "parachuted" down into the body to a place adjacent the desired implant location. Specification as filed, p. 2, ll. 4-7. The prosthetic valve is then secured in place by traditional knot tying with the sutures. Specification as filed, p. 2, ll. 7-8. The process of tying the sutures can be time consuming and labor intensive as doctors often use three to ten knots per suture, and twelve to eighteen sutures are typically used for such procedures. Specification as filed, p. 2, ll. 4-9. The application therefore provides devices and methods that reduce or eliminate the need to manually tie sutures *in situ* in order to attach a prosthesis to a first mass.

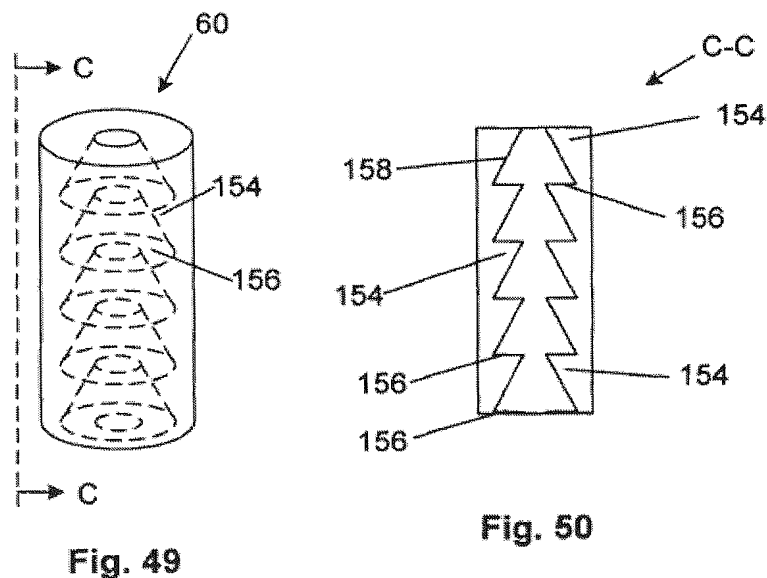
In one embodiment, the invention includes an elongate attachment device, such as a suture 6, having one or more digitations, detents, or pawls 160 fixedly attached to a filament 162. Specification as filed, p. 29, ll. 15-16.



Specification as filed, p. 29, ll. 15-16; FIGS. 52-55. As illustrated in FIGS. 52-53, digitations, detents, or pawls 160 can be formed in a variety of shapes and sizes. A prosthesis including a gasket body 40 can be provided with receptacles, such as cans 60, that are configured to receive the elongate attachment devices therethrough.



Specification as filed, p. 17, ll. 8-12; FIG. 23. Cans 60 can be deformable cylinders. Specification as filed, p. 17, ll. 8-12. Cans 60 can have teeth formed on the internal surface thereof that are configured to engage with digitations, detents, or pawls 160. Specification as filed, p. 29, ll. 9-13. FIGS. 49 and 50 show possible configurations of internal teeth for cans 60.



Forming cans 60 with teeth that can engage pawls 160 allows sutures 6 to be self-fixturingly ratcheted through cans 60, thereby securing the gasket body 40 at a desired implant location.

This eliminates the need to manually tie the free ends of sutures 6 in order to secure the gasket body *in situ*.

### **Independent Claim 1**

Claim 1 recites a heart valve device for connection to a first mass. The heart valve device includes a gasket body with a complementary attachment device. An elongate attachment device is provided. The elongate attachment device has sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site. A receptacle on the gasket body includes a ratchet tooth for self-ratchetedly engaging one or more digitations, detents, or pawls on the elongate attachment device. The digitations, detents, or pawls are located at an intermediate location between opposite ends of the elongate attachment device.

The following table parses the language of claim 1 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 1 reads on the specification and drawings.

Claim 1 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve device for connection to a first mass comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
a gasket body comprising an annular wall defining a gasket radius around a longitudinal axis central to the gasket body, the wall defining first and	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90

second edges,	p. 29, l. 22 - p. 32, l. 23 p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	
the gasket body further comprising a sewing ring including a skirt extending radially outwardly from the first edge and a complementary attachment device in the sewing ring, and	p. 21, l. 1 - p. 23, l. 2 p. 35, ll. 3-10 p. 38, ll. 21-22 p. 44, ll. 10-15	FIGS. 25-27, 76, 81-83, 97
an elongate attachment device comprising one or more digitations, detents, or pawls located at an intermediate location between opposite ends of the elongate attachment device, the elongate attachment device having sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site,	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125
wherein the complementary attachment device comprises an inner attachment radius and an outer attachment radius,	p. 18, l. 9 - p. 19, l. 4 p. 26, ll. 3-12 p. 44, ll. 3-15	FIG. 23
wherein the gasket radius, the inner attachment radius and the outer attachment radius are measured from the longitudinal axis, and wherein the outer attachment radius is greater than the gasket radius, and	p. 18, l. 9 - p. 19, l. 4 p. 26, ll. 3-12 p. 44, ll. 3-15	FIG. 23
wherein the complementary attachment device comprises a receptacle, the receptacle comprising a ratchet tooth for self-ratchetedly engaging the one or more digitations,	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124

detents, or pawls on the elongate attachment device received therethrough.		
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### **Independent Claim 32**

Claim 32 recites a heart valve device for connection to a first mass. The heart valve device includes a gasket body with a complementary attachment device. An elongate attachment device is provided. The elongate attachment device has sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site. A can on the gasket body includes a ratchet tooth for self-ratchetedly engaging one or more digitations, detents, or pawls on the elongate attachment device. The digitations, detents, or pawls are located at an intermediate location between opposite ends of the elongate attachment device.

The following table parses the language of claim 32 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 32 reads on the specification and drawings.

Claim 32 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve device for connection to a first mass comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
a gasket body comprising an annular wall defining a gasket radius around a longitudinal axis central to the gasket body, the wall defining first and second edges,	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17 p. 29, l. 22 - p. 32, l. 23	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90

	p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	
the gasket body further comprising a sewing ring including a skirt extending radially outwardly from the first edge and a complementary attachment device, and	p. 21, l. 1 - p. 23, l. 2 p. 35, ll. 3-10 p. 38, ll. 21-22 p. 44, ll. 10-15	FIGS. 25-27, 76, 81-83, 97
an elongate attachment device comprising a plurality of digitations, detents, or pawls located at an intermediate location between opposite ends of the elongate attachment device, the elongate attachment device having sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site,	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125
wherein the complementary attachment device comprises an inner attachment radius and an outer attachment radius,	p. 18, l. 9 - p. 19, l. 4 p. 26, ll. 3-12 p. 44, ll. 3-15	FIG. 23
wherein the gasket radius, the inner attachment radius and the outer attachment radius arc measured from the longitudinal axis, and wherein the outer attachment radius is greater than the gasket radius, and	p. 18, l. 9 - p. 19, l. 4 p. 26, ll. 3-12 p. 44, ll. 3-15	FIG. 23
wherein the complementary attachment device further comprises a can and the can is fixedly attached to the gasket body, the can comprising a ratchet tooth for self-ratchetedly engaging the digitations, detents, or pawls on the elongate attachment device when the elongate attachment device is received through the can.	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124

**Independent Claim 37**

Claim 37 recites a heart valve device for connection to a first mass. The heart valve device includes a gasket body with a complementary attachment device. An elongate attachment device is provided. The elongate attachment device has sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site. A can on the gasket body includes a plurality of ratchet teeth for self-ratchetedly engaging one or more digitations, detents, or pawls on the elongate attachment device. The digitations, detents, or pawls are located at an intermediate location between opposite ends of the elongate attachment device.

The following table parses the language of claim 37 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 37 reads on the specification and drawings.

Claim 37 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve device for connection to a first mass comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
a gasket body comprising an annular wall defining a gasket radius around a longitudinal axis central to the gasket body, the wall defining first and second edges,	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17 p. 29, l. 22 - p. 32, l. 23 p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90

the gasket body further comprising a sewing ring including a skirt extending radially outwardly from the first edge and a complementary attachment device, and	p. 21, l. 1 - p. 23, l. 2 p. 35, ll. 3-10 p. 38, ll. 21-22 p. 44, ll. 10-15	FIGS. 25-27, 76, 81-83, 97
an elongate attachment device comprising a plurality of digitations, detents, or pawls located at an intermediate location between opposite ends of the elongate attachment device, the elongate attachment device having sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site,	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125
wherein the complementary attachment device comprises an inner attachment radius and an outer attachment radius,	p. 18, l. 9 - p. 19, l. 4 p. 26, ll. 3-12 p. 44, ll. 3-15	FIG. 23
wherein the gasket radius, the inner attachment radius and the outer attachment radius are measured from the longitudinal axis, and wherein the outer attachment radius is greater than the gasket radius, and	p. 18, l. 9 - p. 19, l. 4 p. 26, ll. 3-12 p. 44, ll. 3-15	FIG. 23
wherein the complementary attachment device further comprises a can and the can comprises a plurality of ratchet teeth for self-ratchetedly engaging the digitations, detents, or pawls on the elongate attachment device when the elongate attachment device is received through the can.	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124

**Independent Claim 74**

Claim 74 recites a heart valve device for connection to a first mass. The heart valve device includes a gasket body with a discrete receptacle attached thereto. An elongate attachment device is provided. The elongate attachment device has sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site. The discrete receptacle on the gasket body includes teeth elements comprising shelves and slopes for self-ratchetedly engaging the attachment device through the receptacle. The digitations, detents, or pawls are located at an intermediate location between opposite ends of the elongate attachment device.

The following table parses the language of claim 59 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 74 reads on the specification and drawings.

Claim 74 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve device for connection to a first mass comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
a gasket body comprising an annular wall covered by fabric,	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17 p. 29, l. 22 - p. 32, l. 23 p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90

an elongate attachment device comprising a plurality of digitations, detents, or pawls located at an intermediate location between opposite ends of the elongate attachment device, the elongate attachment device having sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site, and	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125
a discrete receptacle attached to the gasket body for receiving the elongate attachment device therethrough, the receptacle comprising teeth elements comprising shelves and slopes for self-fixturingly ratcheting the attachment device through the receptacle.	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124

### **Independent Claim 96**

Claim 96 recites a heart valve device for connection to a first mass. The heart valve device includes an annular body including a wall with a plurality of receptacles thereon. A plurality of elongate attachment devices is provided. The elongate attachment devices have sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site. The receptacles are provided with an element defining a shelf and a slope. The elongate attachment devices include a detent. The detents are located at an intermediate location between opposite ends of the elongate attachment device.

The following table parses the language of claim 96 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 96 reads on the specification and drawings.

Claim 96 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve device for connection to a first mass, comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
an annular body comprising a wall defining a circumference;	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17 p. 29, l. 22 - p. 32, l. 23 p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90
a plurality of receptacles spaced apart around the circumference of the wall, each receptacle comprising an element defining a shelf and a slope; and	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124
a plurality of elongate attachment devices receivable through the receptacles, each attachment device comprising a detent for self-fixturingly ratcheting through a respective receptacle, the elongate attachment devices having sufficient length such that the annular body can be parachuted down the elongate attachment devices to an implantation site;	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125

<p>wherein each attachment device comprises a plurality of detents spaced apart along a length of the attachment device at an intermediate location between opposite ends of the respective attachment device.</p>	<p>p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15</p>	<p>FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125</p>

### **Independent Claim 113**

Claim 113 recites a heart valve assembly for implantation within a biological annulus. The heart valve assembly includes a crown carrying leaflets. The assembly further includes a gasket body with a plurality of fixturing devices attached thereto. A plurality of elongate attachment devices are provided. The elongate attachment devices are receivable through respective fixturing devices and have sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site. The elongate attachment devices include a plurality of detents.

The following table parses the language of claim 113 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 113 reads on the specification and drawings.

Claim 113 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve assembly for implantation within a biological annulus, comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
a heart valve assembly comprising a crown carrying leaflets;	p. 50, l. 21 - p. 51, l. 19	FIGS. 128-130
a gasket body comprising an annular wall and a sewing ring attached to the annular wall, the sewing ring comprising a skirt extending radially outwardly from an edge of the wall;	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17 p. 29, l. 22 - p. 32, l. 23 p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90
a plurality of fixturing devices for attaching the gasket body to the biological annulus; and	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124
a plurality of elongate attachment devices receivable through respective fixturing devices and having sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site,	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125

	p. 41, l. 17 - p. 50, l. 15	
wherein each attachment device comprises a plurality of detents spaced apart along a length of the attachment device at an intermediate location between opposite ends of the respective attachment device.	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124

**Independent Claim 116**

Claim 116 recites a heart valve assembly for implantation within a biological annulus. The heart valve assembly includes a crown carrying leaflets. The assembly further includes a gasket body with a plurality of fixturing devices attached thereto. Each fixturing device comprises an element defining a shelf and a slope located at an intermediate location between opposite ends of the respective attachment device. Each fixturing device includes teeth elements. A plurality of elongate attachment devices are provided. The elongate attachment devices have sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site. Each attachment device comprises a detent for self-fixturingly ratcheting through a respective fixturing device.

The following table parses the language of claim 116 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 116 reads on the specification and drawings.

Claim 116 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve assembly for implantation within a biological annulus, comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
a heart valve assembly comprising a crown carrying leaflets;	p. 50, l. 21 - p. 51, l. 19	FIGS. 128-130
a gasket body comprising an annular wall and a sewing ring attached to the annular wall, the sewing ring comprising a skirt extending radially outwardly from an edge of the wall;	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17 p. 29, l. 22 - p. 32, l. 23 p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90
a plurality of fixturing devices for attaching the gasket body to the biological annulus; and	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124
a plurality of elongate attachment devices receivable through respective fixturing devices,	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125

	p. 41, l. 17 - p. 50, l. 15	
the elongate attachment devices having sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site,	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125
wherein each fixturing device comprises an element defining a shelf and a slope located at an intermediate location between opposite ends of the respective attachment device,	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124
the fixturing devices configured for receiving respective elongate attachment devices therethrough,	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124
each attachment device comprising a detent for self-fixturingly ratcheting through a respective fixturing device; and	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125

wherein each fixturing device comprises teeth elements for engaging the detent on the respective attachment device.	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124

**Independent Claim 117**

Claim 117 recites a heart valve assembly for implantation within a biological annulus. The heart valve assembly includes a crown carrying leaflets. The assembly further includes a gasket body with a plurality of fixturing devices attached thereto. Each fixturing device includes a plurality of shelves and slopes located at an intermediate location between opposite ends of the respective attachment device. A plurality of elongate attachment devices are provided. The elongate attachment devices have sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site. Each attachment device comprises a detent for self-fixturingly ratcheting through a respective fixturing device.

The following table parses the language of claim 117 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 117 reads on the specification and drawings.

Claim 117 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve assembly for implantation within a biological annulus, comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
a heart valve assembly comprising a crown carrying leaflets;	p. 50, l. 21 - p. 51, l. 19	FIGS. 128-130
a gasket body comprising an annular wall and a sewing ring attached to the annular wall, the sewing ring comprising a skirt extending radially outwardly from an edge of the wall;	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17 p. 29, l. 22 - p. 32, l. 23 p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90
a plurality of fixturing devices for attaching the gasket body to the biological annulus; and	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124
a plurality of elongate attachment devices receivable through respective fixturing devices,	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125

	p. 41, l. 17 - p. 50, l. 15	
the elongate attachment devices having sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site,	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125
wherein each fixturing device comprises an element defining a shelf and a slope,	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124
the fixturing devices configured for receiving respective elongate attachment devices therethrough,	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124
each attachment device comprising a detent located at an intermediate location between opposite ends of the respective attachment device for self-fixturingly ratcheting through a respective fixturing device; and	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125

wherein each fixturing device comprises a plurality of shelves and slopes.	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124

**Independent Claim 119**

Claim 119 recites a heart valve device for connection to a first mass. The heart valve device includes an annular body with a plurality of receptacles spaced apart on a wall of the annular body. Each receptacle includes an element defining a shelf and a slope. A plurality of elongate attachment devices is provided. The elongate attachment devices have sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site. One or more digitations, detents, or pawls are provided on the elongate attachment devices.

The following table parses the language of claim 119 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 119 reads on the specification and drawings.

Claim 119 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve device for connection to a first mass, comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
an annular body comprising a wall defining a circumference;	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17 p. 29, l. 22 - p. 32, l. 23 p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90
a plurality of receptacles spaced apart around the circumference of the wall, each receptacle comprising an element defining a shelf and a slope; and	p. 21, l. 1 - p. 23, l. 2 p. 35, ll. 3-10 p. 38, ll. 21-22 p. 44, ll. 10-15	FIGS. 25-27, 76, 81-83, 97
a plurality of elongate attachment devices receivable through the receptacles and having sufficient length such that the annular body can be parachuted down the elongate attachment devices to an implantation site, each elongate attachment device comprising a plurality of digitations, detents, or pawls at an intermediate location between opposite ends of the respective attachment device for self-fixturingly ratcheting through a respective receptacle.	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125

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**Independent Claim 125**

Claim 125 recites a heart valve assembly for implantation within a biological annulus. The heart valve assembly includes a crown carrying leaflets. The assembly further includes a gasket body with a plurality of fixturing devices attached thereto. A plurality of elongate attachment devices are provided. The elongate attachment devices have sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site. Each attachment device comprises a plurality of digitations, detents, or pawls for self-fixturingly ratcheting through a respective fixturing device.

The following table parses the language of claim 120 and provides one example of how it reads on particular portions of the specification and the drawings. There may be other ways in which claim 125 reads on the specification and drawings.

Claim 125 Text	Specification Reference [paragraph numbers in specification]	Drawing Reference
A heart valve assembly for implantation within a biological annulus, comprising:	p. 4, l. 22 p. 5, ll. 16-17 p. 6, ll. 4-5 p. 50, l. 21 - p. 51, l. 19	FIGS. 12-14, 21-25, 56-66, 69-75, 85-90, 128-130
a heart valve assembly comprising a crown carrying leaflets;	p. 50, l. 21 - p. 51, l. 19	FIGS. 128-130
a gasket body comprising an annular wall and a sewing ring attached to the annular wall, the sewing ring comprising a skirt extending radially outwardly from an edge of the wall;	p. 4, ll. 22-23 p. 6, ll. 9-16 p. 15, l. 7 - p. 17, l. 12 p. 18, l. 9 - p. 19, l. 4 p. 28, ll. 4-17 p. 29, l. 22 - p. 32, l. 23	FIGS. 12-14, 21-25, 56-66, 69-75, and 85-90

	p. 34, ll. 7-20 p. 38, ll. 18-22 p. 40, ll. 8-18	
a plurality of fixturing devices on the gasket body for attaching the gasket body to the biological annulus; and	p. 4, l. 22 - p. 5, l. 15 p. 15, ll. 7-23 p. 17, l. 5 - p. 19, l. 4 p. 20, ll. 18-22 p. 32, l. 16 - p. 35, l. 2 p. 50, ll. 19-20	FIGS. 23-51, 56-72, 88-92, 95-120, 123-124
a plurality of elongate attachment devices receivable through respective fixturing devices and having sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site,	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125
each elongate attachment device comprising a plurality of digitations, detents, or pawls at an intermediate location between opposite ends of the respective attachment device for self-fixturingly ratcheting through a respective fixturing device.	p. 2, ll. 4-9 p. 17, ll. 8-15 p. 18, ll. 3-8 p. 20, ll. 13-22 p. 21, ll. 10-15 p. 23, ll. 3-10 p. 24, ll. 4-8 p. 27, ll. 12-15 p. 29, ll. 14-21 p. 41, l. 17 - p. 50, l. 15	FIGS. 52-55, 88-90, 93-95, 104, 109-114, 119-120, 124-125

***VI. Grounds of Rejection to be Reviewed on Appeal (37 C.F.R. § 41.37(c)(1)(vi))***

In the final Office Action mailed July 24, 2009, the Examiner rejected claims 96, 113-114, 119-123, 125-126, and 128-130 under 35 U.S.C. § 103(a), as allegedly being unpatentable over U.S. Patent No. 6,241,765 to Griffin et al. ("Griffin") in view of U.S. Patent No. 4,548,202 to Duncan ("Duncan") or U.S. Patent No. 6,589,279 to Anderson et al. ("Anderson").

The Examiner rejected claims 1-2, 9-10, 16, 21, 29-32, 34, 37, 41, 51-53, 56, 74, 116-118, 124, and 127 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Griffin in view of U.S. Patent No. 6,066,160 to Colvin et al. ("Colvin") and further in view of Duncan.

Accordingly, there are two grounds of rejection to be reviewed on appeal:

- A. The rejection of claims 96, 113-114, 119-123, 125-126, and 128-130 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Griffin in view of Duncan or Anderson, and
- B. The rejection of claims 1-2, 9-10, 16, 21, 29-32, 34, 37, 41, 51-53, 56, 74, 116-118, 124, and 127 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Griffin in view of U.S. Patent No. 6,066,160 to Colvin et al. ("Colvin") and further in view of Duncan.

***VII. Argument (37 C.F.R. § 41.37(c)(1)(vii))***

**A. The rejection of claims 96, 113-114, 119-123, 125-126, and 128-130 under 35 U.S.C. § 103(a), as allegedly being unpatentable over U.S. Patent No. 6,241,765 to Griffin et al. ("Griffin") in view of U.S. Patent No. 4,548,202 to Duncan ("Duncan") or U.S. Patent No. 6,589,279 to Anderson et al. ("Anderson"), is in error.**

Appellants' arguments herein focus on independent claims 96, 113, 119, and 125. Claims 97-107 depend from and add features to claim 96, and are therefore patentable for at least the same reasons as claim 96. Claim 114 depends from and adds features to claim 113, and is therefore patentable for at least the same reasons as claim 113. Claims 120-123 depend from and add features to claim 119, and are therefore patentable for at least the same reasons as claim 119. Claims 126 and 128-130 depend from and add features to claim 125, and are therefore patentable for at least the same reasons as claim 125.

***1. The Examiner's obviousness rejection***

In the final Office Action mailed July 24, 2009, the Examiner rejected claims 96, 113-114, 119-123, 125-126, and 128-130 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Griffin in view of Duncan or Anderson. Final Office Action, pp. 2-4.

The Examiner asserts that Griffin discloses:

- an annular body (the shoulder 57 or ring 29),
- receptacles (openings 96 and the shoulder portions therearound),
- a shelf (surface 82),
- attachment devices (pins 91),
- detents (barbs 94 and/or heads 92).

The Examiner also asserts that Griffin discloses elongate attachment devices having sufficient length such that the annular body can be parachuted down the elongate attachment devices to an implantation site. Specifically, the Examiner asserts that the "parachuting" language "does not clearly require a particular length" and is therefore considered to read on Griffin.

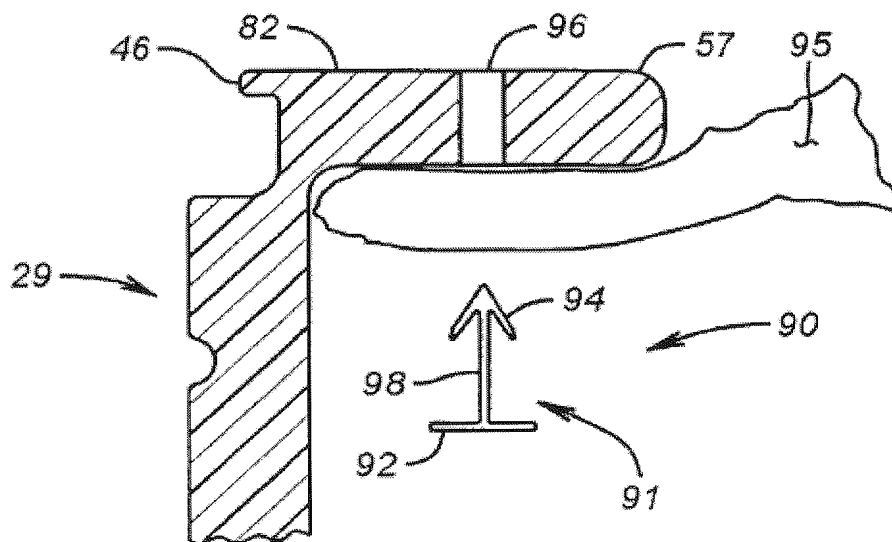
The Examiner admits that Griffin does not disclose "detents spaced apart along a length of the attachment device at an intermediate location between opposite ends of the respective attachment device," which is recited in independent claims 96, 113, 119, and 125. Final Office Action, p. 3. The Examiner relies on Duncan or Anderson to remedy this acknowledged deficiency of Griffin.

The Examiner characterizes Duncan and Anderson as teaching that it was known in the prior art "to make elongate attachment devices that have detents along the length thereof" within the tissue fastener art. Final Office Action, p. 3. The Examiner therefore asserts that it would have been obvious to substitute the fasteners of Griffin for the fasteners of Duncan or Anderson "because such a substitution would provide a predictable result." Final Office Action, p. 3.

## ***2. Summary of Cited References***

### ***(i) U.S. Patent No. 6,241,765 – "Griffin"***

U.S. Patent No. 6,241,765 to Griffin ("Griffin") is directed to a mechanical heart valve that uses staples 79 or pins 91 to secure a stiffening ring to a patient's heart tissue. Griffin, col. 1, ll. 45-55. Prosthetic heart valve 10 includes an annular valve body 14 and a stiffening ring 29.



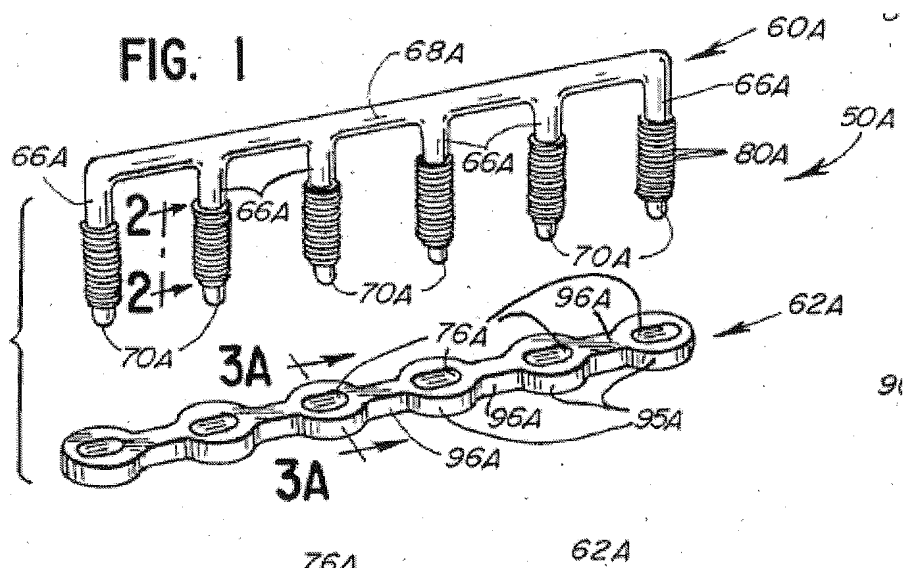
Griffin, col. 2, ll. 59-61; FIG. 7. The stiffening ring 29 is delivered to the implantation site, and then pins 91 are inserted through the patient's heart tissue from below the stiffening ring 29 to secure the stiffening ring 29 to the tissue. Griffin, col. 5, ll. 23-30. Pins 91 are sized such that when pin 91 is inserted through the tissue 95 and the shoulder 57 of sewing ring 29, the barbs 94 extend through opening 96 and engage the surface 82 of the shoulder 57. Griffin, col. 5, ll. 28.

Griffin explains that "hand sewing of [a] replacement heart valve into position using traditional suture rings . . . takes a significant amount of time and skill by the heart surgeon." Griffin, col. 1, ll. 31-35. To remedy these problems, Griffin discloses a heart valve and method of insertion that "significantly reduces the amount of time for a surgical procedure" by utilizing staples and pins inserted through the valve and into the body using an attachment device. Griffin, col. 1, ll. 36-38. In operation, the staples 79 or pins 91 are directly inserted into a patient's heart tissue to secure the valve *in situ*. Griffin, col. 5, ll. 19-51. An attachment device 100 carrying staples 79 or pins 91 is delivered to the location of the

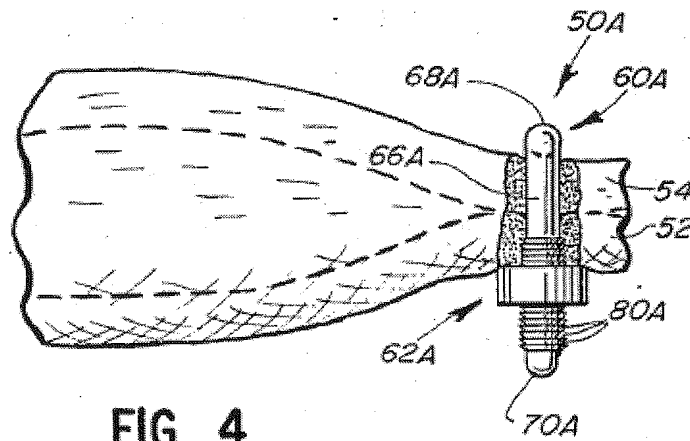
mechanical valve and the attachment device 100 is then actuated to implant the staples 79 or pins 91 to secure the valve to the heart tissue. Griffin, col. 6, ll. 51-59; FIG. 8.

**(ii) U.S. Patent No. 4,548,202 – “Duncan”**

U.S. Patent No. 4,548,202 to Duncan (“Duncan”) is directed to fasteners to hold together portions of mammalian tissue, such as the sides of a wound or incision, to facilitate healing of the wound or incision. Duncan, col. 2, ll. 51-54. The fastener 50A includes an elongate clamping member 68A and a plurality of parallel legs 66A extending therefrom.



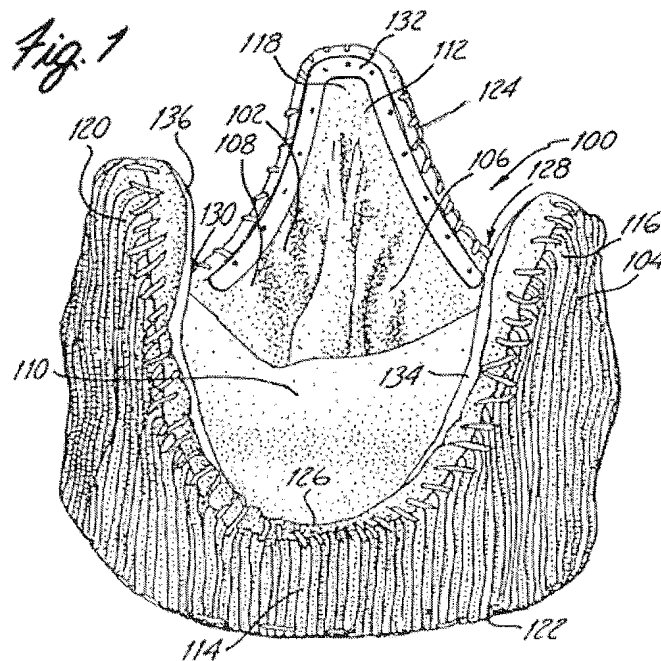
Duncan, col. 5, ll. 27; FIG. 1. The legs 66A are configured to be received by receivers 62A, whereby two tissue portions can be sandwiched between clamping portion 68A and the receivers 62A. Duncan, col. 5, ll. 34-54. As shown in FIG. 4 of Duncan, the fastener legs 66A extend through two pieces of mammalian tissue 52 and 54 and extend only slightly from the tissue.



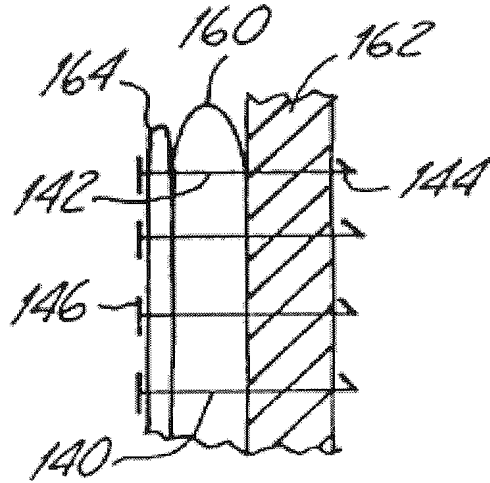
**FIG. 4**

(iii) *U.S. Patent No. 6,589,279 – “Anderson”*

U.S. Patent No. 6,328,763 to Anderson et al. (“Anderson”) is directed to a heart valve prosthesis 100 that is secured to the aortic wall by fasteners 140.



Anderson, col. 6, ll. 6-47; FIG. 1. Fasteners 140 are of a length that closely matches the combined thickness of the aortic wall 162 and the valve wall 160.



Anderson, FIG. 4A; col. 38-47. Heart valve prosthesis 100 is first delivered to a native annulus and only after the prosthesis 100 is properly aligned in the annulus are fasteners 140 inserted through the commissural supports 160 and aortic wall 162 to attach the prosthesis to the body. Anderson, col. 9, ll. 47-63.

### ***3. The Examiner's Rejection is in Error and Must be Reversed***

The Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *In re Piasecki*, 745 F.2d 1468, 1471-73, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984). "Rejections on obviousness cannot be sustained by merely conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006). In determining whether a claim is obvious over the prior art:

the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined.

*Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966).

During examination, an Examiner is required to give the words of a *claim being examined* their broadest *reasonable* interpretation consistent with the specification, and consistent with the interpretation that would have been reached by a person of ordinary skill in the art. *See, e.g., In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, 70 U.S.P.Q.2d 1827, 1830 (Fed. Cir. 2004) (emphasis added). A word must be given its plain meaning unless the plain meaning is inconsistent with the specification, *i.e.*, the "ordinary and customary meaning" given to the term by those of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 75 U.S.P.Q.2d 1321, 1326 (Fed. Cir. 2005)(*en banc*).

Here, the Examiner has failed to establish a *prima facie* case of obviousness because none of the cited references, taken alone or in combination, teach, disclose, or suggest elongate attachment devices having sufficient length such that an annular body can be parachuted down the elongate attachment devices to an implantation site. Even under the broadest reasonable interpretation of the term "parachuted," the Examiner must provide a meaning to the term that is consistent with the specification and how those skilled in the art use the term. The Examiner's assertion that the fasteners of Griffin meet this limitation relies on an interpretation of the term "parachuted" that is inconsistent with the ordinary and customary meaning of that term to one of ordinary skill in the art and is also inconsistent with use of the term in the specification of the present application. *See, e.g., In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d at 1364. Furthermore, even if the Examiner's interpretation was consistent with the ordinary and customary meaning, which it is not, the Examiner has failed to articulate how an annular member could be parachuted down the fastening members of Griffin, Duncan, or Anderson.

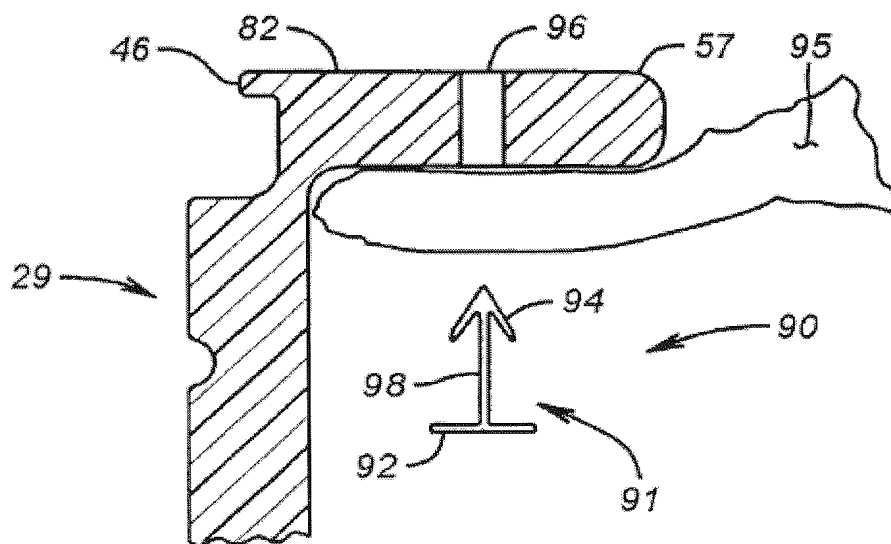
In the final Office Action, the Examiner states that "Griffin also discloses elongate attachment devices having sufficient length such that an annular body can be parachuted down [the elongate attachment devices] to the implantation site," Final Office Action, p. 3. Specifically, the Examiner explains that "this claim language *does not clearly require a particular length* and is considered read on by the fasteners of Griffin." Final Office Action, p. 3 (emphasis added). However, in the art of prosthetic heart valves and implantation of prosthetic heart valves, the term "parachuting to an implantation site" is commonly understood to mean delivering a portion of a heart valve from a position removed from a desired implantation site in the body to a position adjacent to the desired implantation site. Paragraph [0003] of the specification as filed describes such procedures, which are typical in the art of prosthetic heart valve implantation and design:

Known heart valve replacement techniques include individually passing sutures through the fibrous tissue or desired placement site within the valve annulus to form an array of sutures. Free ends of the **sutures are extended out of the thoracic cavity** and laid, spaced apart, on the patient's body. The free ends of the **sutures are then individually threaded through a flange of the sewing ring**. Once all sutures have been run through the sewing ring (typically 12 to 18 sutures), all the **sutures are pulled up taught and the prosthetic valve is slid or "parachuted" down into place adjacent the placement site tissue**.

The concept of "parachuting" is also discussed in the Anderson patent, although not in connection with elongate attachment devices. Anderson discloses performing a transverse aortotomy (cutting an opening in the aorta) to make the natural aortic valve accessible through the aorta. Anderson, col. 9, ll. 39-41. Anderson then explains that "[f]or placement at the aortic annulus, the prosthesis can be parachuted down the severed aorta." The Anderson prosthesis is therefore delivered from a location removed from the aortic annulus to the aortic annulus by sliding the prosthesis down an aorta. This use of the term "parachuted"

in Anderson is consistent with the use of that term in the present application and further demonstrates that the ordinary and customary meaning of the term "parachuted" to one of skill in the art is "delivering a portion of a heart valve from a position removed from a desired implantation site in the body to a position adjacent to the desired implantation site."

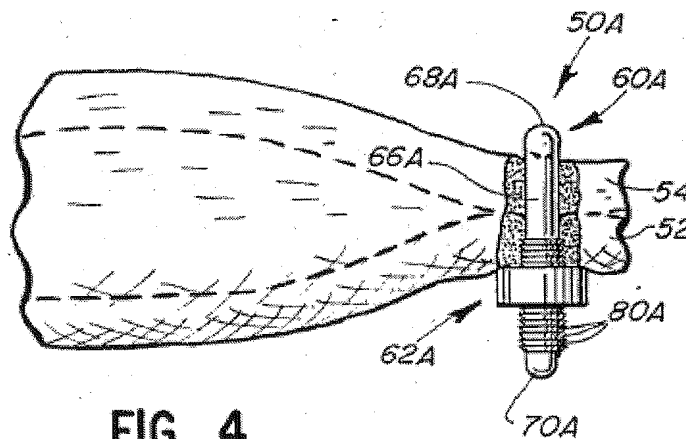
Neither Griffin, Duncan, nor Anderson disclose elongate attachment devices that have sufficient length to allow a annular member to be parachuted down the attachment device. As illustrated in FIG. 7, Griffin discloses pins 91 that are configured to extend through a patient's heart tissue and a stiffening ring 29 to attach the stiffening ring 29 to the heart tissue.



Griffin, FIG. 7; col. 5, ll. 19-23. The stiffening ring 29 is delivered to the implantation site, and only then are pins 91 inserted from the patient's heart tissue from below the stiffening ring 29 to secure the stiffening ring 29 to the tissue. Griffin, col. 5, ll. 23-30. Pins 91 are sized such that when pin 91 is inserted through the tissue 95 and the shoulder 57 of sewing ring 29, the barbs 94 extend through opening 96 and engage the surface 82 of the shoulder 57. Griffin, col. 5, ll. 28. Thus, pins 91 are of a length that allows them to extend only to the

top of shoulder 57. The pins are not of sufficient length such that the stiffening ring 91 can be parachuted down the pins to an implantation location.

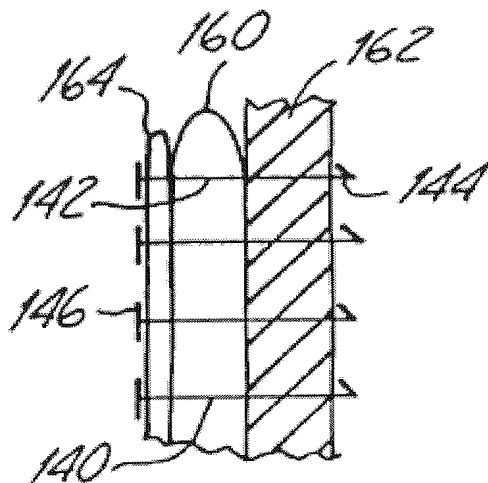
Duncan discloses fasteners to hold together portions of mammalian tissue, such as the sides of a wound or incision, to facilitate healing of the wound or incision. Duncan, col. 2, ll. 51-54. Duncan discloses a fastener 50A that includes a fastening member 60A and a receiver 62A. Duncan, col. 5, ll. 14-15. As shown in FIG. 4 of Duncan, the fastener legs 66A extend through two pieces of mammalian tissue 52 and 54 and extend only slightly from the tissue.



**FIG. 4**

Thus, even if the pins 91 of Griffin were replaced by the fastener legs 66A of Duncan, fastener legs 66A are not of sufficient length to allow the ring 29 of Griffin to be parachuted down the fastener legs 66A to an implantation site.

Anderson discloses a heart valve prosthesis 100 that is secured to the aortic wall by fasteners 140. Anderson, col. 6, ll. 6-47. Like the Griffin pins, fasteners 140 are of a length that closely matches the combined thickness of the aortic wall 162 and the valve wall 160.



Anderson, FIG. 4A; col. 38-47. Also like Griffin, heart valve prosthesis 100 of Anderson is first delivered to a native annulus and only after the prosthesis 100 is properly aligned in the annulus are fasteners 140 inserted through the commissural supports 160 and aortic wall 162 to attach the prosthesis to the body. Anderson, col. 9, ll. 47-63. The fasteners 140 are not of sufficient length to allow the ring 29 of Griffin to be parachuted down the fasteners 140 to the native annulus. Indeed, as noted above, valve prosthesis 100 of Anderson is parachuted, that is, delivered, down the aorta to the location of the native annulus. Thus, Anderson understands and discloses the difference between a parachuting structure and a basic fastener.

Thus, even when the term "parachuted" is given its broadest reasonable construction, neither Griffin, Duncan, nor Anderson, taken alone or in combination, teach, disclose, or suggest elongate attachment devices having sufficient length such that an annular body can be parachuted down the elongate attachment devices to an implantation site, as currently recited in claims 96, 113, 119, and 125.

Furthermore, the Examiner's attempts to combine the references in this manner violates the principle that the entire claim must be considered as a whole. *See* MPEP

2141.02. Regardless of the exact length of the elongate attachment members, the Examiner's focus on the short fasteners of Griffin, Duncan, and Anderson improperly ignores subject matter that is literally recited in the claims, inherent in the claims, and detailed in the specification. *See* MPEP 2141.02.V. The specification of the present application discusses typical prosthetic valve implantation procedures wherein a portion of the valve is "parachuted" down sutures from a position removed from the implantation location to a position adjacent to the implantation location. Specification as filed, p. 1, l. 21 - p. 2, l. 9. The specification explains that, conventionally, the sutures were then manually tied to secure the valve in the implantation location, which is a time consuming process. Specification as filed, p. 2, ll. 4-9. The application thus seeks to complement existing suturing devices in order to reduce fixturing times by providing a fixturing device that uses "a technique familiar to the users of existing devices," i.e., parachuting. Specification as filed, p. 4, ll. 11-14. Thus, the meaning of delivering a prosthesis by parachuting, i.e., sliding a prosthesis from a position removed from an implantation location to a position adjacent to the implantation location, is inherent in the claims of the present application, each of which includes the "parachuted" limitation. None of the cited prior art references recognize that manual suture tying in a parachuting implantation can be avoided by using digitations, detents, or pawls in conjunction with an elongate member and receptacles configured to self-fixturingly ratchet digitations, detents, or pawls into place. By ignoring the entire "parachuted" recitation of the claims simply because the claims provide no specific unit measure of length of the elongate attachment members, the Examiner has improperly failed to consider the invention as a whole when comparing the claims with the prior art.

Claims 97-107 depend from and add features to claim 96, and are therefore patentable for at least the same reasons as claim 96. Claim 114 depends from and adds features to claim 113, and is therefore patentable for at least the same reasons as claim 113. Claims 120-124 depend from and add features to claim 119, and are therefore patentable for at least the same reasons as claim 119. Claims 126-130 depend from and add features to claim 125, and are therefore patentable for at least the same reasons as claim 125.

***B. The rejection of claims 1-2, 9-10, 16, 21, 29-32, 34, 37, 41, 51-53, 56, 74, 116-118, 124, and 127 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Griffin in view of U.S. Patent No. 6,066,160 to Colvin et al. (“Colvin”) and further in view of Duncan, is in error.***

Appellants’ arguments herein focus on independent claims 1, 32, 37, 74, 116, and 117. Claims 2, 9-10, 16, 21, 29-31, 34, 41, 51-53, 56 depend from and add features to claim 1, and are therefore patentable for at least the same reasons as claim 1. Claim 118 depends from and adds features to claim 117, and is therefore patentable for at least the same reasons as claim 117. Claim 124 depends from and adds features to claim 119, and is therefore patentable for at least the same reasons as claim 119, which are detailed above in Section VII.A.3. Claim 127 depends from and adds features to claim 125, and is therefore patentable for at least the same reasons as claim 125, which are detailed above in Section VII.A.3. Claims 124 and 127 are also separately patentable because neither Griffin, Colvin, nor Duncan, taken alone or in combination, teach or disclose the features described in claims 124 and 127.

***1. The Examiner’s obviousness rejection***

In the final Office Action mailed July 24, 2009, the Examiner claims 1-2, 9-10, 16, 21, 29-32, 34, 37, 41, 51-53, 56, 74, 116-118, 124, and 127 under 35 U.S.C. § 103(a), as

allegedly being unpatentable over Griffin in view of Colvin and further in view of Duncan. Final Office Action, pp. 4-5.

The Examiner asserts that Griffin discloses the features described above with reference to the rejection of claims 96, 113-114, 119-123, 125-126, and 128-130. The Examiner admits that Griffin does not disclose "teeth in each receptacle and/or separate can elements." Final Office Action, p. 4. The Examiner relies on Duncan and Colvin to remedy this acknowledged deficiency of Griffin.

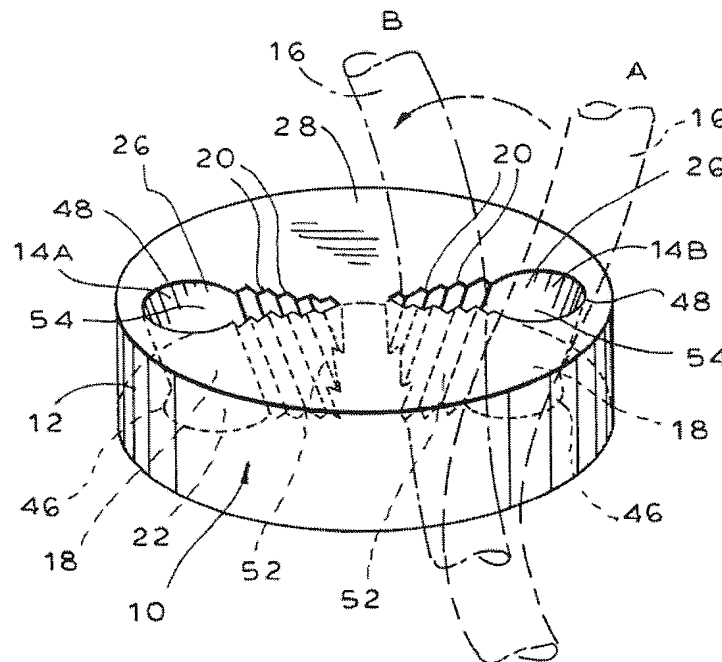
The Examiner states that Colvin teaches that it was known to make separate receptacles that ratchet sutures thereto in the implantation of heart valves. Final Office Action, p. 4. The Examiner further states that Griffin explains that any suitable fastening system of pins and staples can be used therewith, and that Duncan teaches that it was known in the art of tissue fastening to utilize fasteners that have teeth on both the staple legs and in the receptacles. Final Office Action, p. 4.

The Examiner then asserts that it would have been obvious to utilize separate receptacles, as taught by Colvin, that include teeth both on the pin and in the receptacle opening, as taught by Duncan, in order to provide wider ranges of tissue size fastening capabilities to the Griffin device.

## ***2. Summary of Cited References***

Summaries of cited references Griffin, Duncan, and Anderson are provided above with reference to the rejections of claims 96, 113-114, 119-123, 125-126, and 128-130 under 35 U.S.C. § 103(a).

U.S. Patent No. 6,066,160 to Colvin et al. ("Colvin") is directed to apparatuses and systems for securing the ends of sutures. Colvin, col. 4, ll. 30-31. The suture terminating device 10 of Colvin includes a main member 12 having apertures 14(a) and 14(b) positioned therein to facilitate the threading of standard suture 16 therethrough.



Colvin, col. 7, l. 63 – col. 8, l. 1; FIG. 1. As a surgeon draws a suture 16 through the aperture 14, the suture 16 is secured in place by a locking mechanism 18 within that aperture. Colvin, col. 8, ll. 2-4. Apertures 14(a) and 14(b) are housing in the midline of main member 12. Colvin, col. 8, ll. 34-35. In this configuration, the apertures cooperate as pairs, each member receiving one of the two ends of the suture being secured. Colvin, col. 8, ll. 38-40. In some embodiments, the apertures can be lined with ridges or serrations 88 which are generally perpendicular to the aperture's orientation. Colvin, col. 10, ll. 63-66.

**3. The Examiner's Rejection is in Error and Must be Reversed**

"A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art to which the subject matter pertain." 35 U.S.C. §103(a). In *KSR Int'l v. Teleflex* 550 U.S. 398 (2006), the Supreme Court reaffirmed its decision in *Graham v. John Deere* that said to find an invention obvious "the scope and content of the prior art [must] be determined; differences between the prior art and the claims at issue [must] be ascertained; and the level of ordinary skill in the pertinent art [must be] resolved." *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). *Graham* also set forth "secondary considerations" relevant to nonobviousness such as "commercial success, long felt but unsolved needs, [and] failure of others." *Id.* at 17-18.

To guard against impermissible hindsight, the Office must fully articulate its obviousness rejections. See *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006). For instance, the Examiner may not use the challenged claims as a roadmap on how to combine references. If a person of skill in the art would not have identified the proposed combination, or if the proposed modification would have been inoperable, a conclusion of obviousness is improper. Further, "[i]f [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP 2143.01.V (citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

An Examiner must also weigh teachings in favor of combination against teachings against the combination. "A prior art reference that 'teaches away' from the claimed invention is a significant factor to be considered in determining obviousness." MPEP

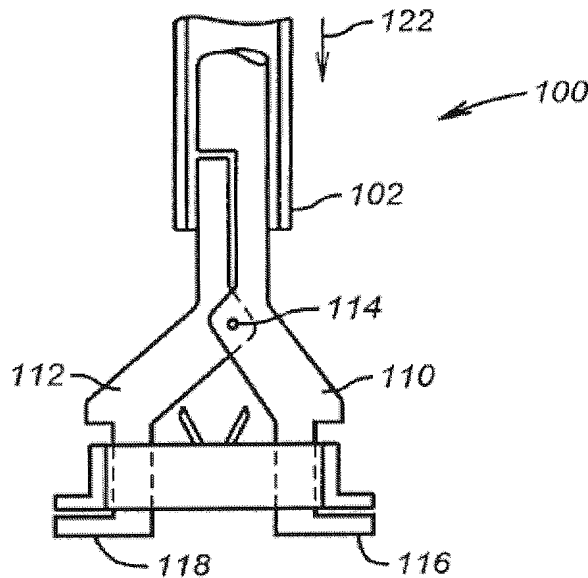
2145.X.D.1. It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983), *see also* MPEP 2145.X.D.2.

The Examiner states that it would have been obvious to utilize receptacles as taught by Colvin in the device taught by Griffin. Final Office Action, p. 4. However, the attachment methods of Colvin and Griffin are not compatible, and Griffin actually teaches away from using the suture methods taught by Colvin.

In the "Description of Related Art" section, Griffin explains that "hand sewing of the replacement heart valve into position using traditional suture rings . . . takes a significant amount of time and skill by the heart surgeon." Griffin, col. 1, ll. 31-35. Griffin then explains that it would be desirable to develop a heart valve and method of insertion that "significantly reduces the amount of time for a surgical procedure. **It would be further desirable if such a surgical procedure did not require the precision of suturing.**" Griffin, col. 1, ll. 36-38.

In the Final Office Action, the Examiner argues that Griffin does not teach away from parachuting or suturing "merely because Griffin says that it takes significant skill and time to suture a heart valve with a suture ring." Final Office Action, p. 5. The Examiner then cites *In re Fulton* for the proposition that "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." Final Office Action, p. 5 (citing *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)). However, this proposition bears no relation to the instant case. Specifically, as noted above,

Griffin expressly denigrates suturing and states that a purpose of the invention is to develop a surgical procedure **that does not require suturing**. Griffin, col. 1, ll. 31-38. Furthermore, Griffin only discloses attaching a heart valve prosthesis to body tissue using a securing device. Griffin, col. 5, ll. 41-59. Griffin is directed to a mechanical heart valve that uses staples 79 or pins 91 to secure a stiffening ring to a patient's heart tissue. Griffin, col. 1, ll. 45-55. The staples 79 or pins 91 are directly inserted into a patient's heart tissue to secure the valve *in situ*. Griffin, col. 5, ll. 19-51. An attachment device 100 carrying staples 79 or pins 91 is delivered to the location of the mechanical valve and the attachment device 100 is then actuated to implant the staples 79 or pins 91 to secure the valve to the heart tissue. Griffin, col. 6, ll. 51-59; FIG. 8.



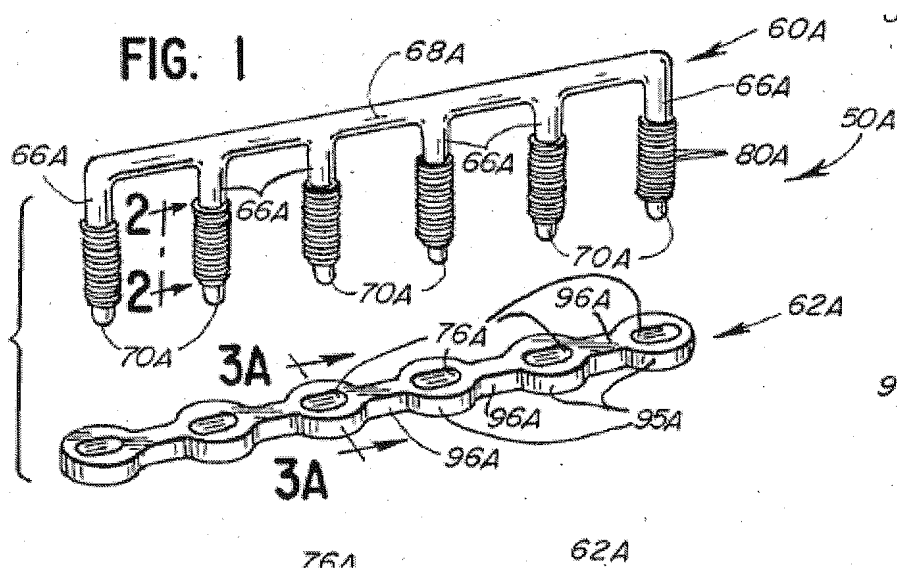
(ENGAGED)

**FIG. 8**

Nowhere does Griffin contemplate or discuss an alternative method that would involve inserting staples 79 or pins 91 with suturing. Because Griffin expressly denigrates

the use of suturing as a method of attaching a heart valve prosthesis to native tissue and is directed to attaching staples or pins using an attachment device, one of ordinary skill in the art would not have combined Colvin, which is directed to devices for securing sutures to an apparatus body, with Griffin. *See In re Grasselli*, 713 F.2d at 743.

Furthermore, Duncan also fails to disclose or suggest can elements or complementary attachment devices including teeth formed in a gasket of a heart valve, as recited in independent claims 1, 32, 37, 74, and 116. Duncan discloses fasteners to hold together portion of mammalian tissue. Duncan, col. 2, ll. 51-54. The fastener includes an elongate clamping member 68A and a plurality of parallel legs 66A extending therefrom. Duncan, col. 5, ll. 27; FIG. 1.



The legs 66A are configured to be received by receivers 62A, whereby two tissue portions can be sandwiched between clamping portion 68A and the receivers 62A. Duncan, col. 5, ll. 34-54. As such, the Duncan apparatus requires a plurality of legs 66A with an elongate clamping member 68A extending therebetween to provide a surface to sandwich tissue. Such

an elongate member is incompatible with the stiffening ring 29 and attachment device 100 of Griffin. The Examiner has provided no articulation of how the elongate clamping member 68A and receivers 62A could be included in the annular body disclosed by Griffin without rendering Griffin unsatisfactory for its intended purpose. The Duncan device depends on the cooperation of elongate attachment member 68A and narrow portions 96A of the receiver 62A to pinch two portions of tissue together. Including the elongate attachment member 68A in the device of Griffin would prohibit the legs 66A from passing through an opening on the stiffening ring of Griffin. Furthermore, the fasteners of Duncan are made from materials that are absorbable by mammalian tissue. Duncan, col. 6, ll. 44-51. As such, using the fasteners of Duncan in place of the pins 91 of Griffin would render the Griffin device inoperable for its intended purpose of securing a prosthetic heart valve in the body. *See* MPEP 2143.01.V ("[i]f [a] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification"). Specifically, as the fasteners of Duncan absorb in the body, the prosthetic valve would loosen or completely separate from the native annulus, which could have fatal results to the patient. For at least these reasons, Duncan therefore fails to remedy the deficiencies of Griffin.

Furthermore, as noted in Section VII.A.3, neither Griffin nor Duncan, taken alone or in combination, teach or suggest elongate attachment devices having sufficient length such that an annular body can be parachuted down the elongate attachment devices to an implantation site, as recited in independent claims 1, 32, 37, 74, 116, 117. As detailed above, one of ordinary skill in the art would not have combined the teachings of Colvin, which are directed to devices for securing sutures to an apparatus body, with Griffin.

Thus, because one of ordinary skill in the art would not have combined Griffin with Colvin, and because neither Griffin nor Duncan, taken alone or in combination, disclose or suggest can elements or complementary attachment devices including teeth formed in a gasket of a heart valve or elongate attachment devices having sufficient length such that an annular body can be parachuted down the elongate attachment devices to an implantation site, the rejection of claims 1, 32, 37, 74, 116, 117, 124, and 127 must be reversed.

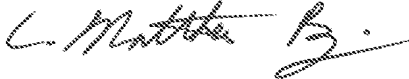
Claims 2, 9-10, 16, 21, 29-31, 34, 41, 51-53, 56 depend from and add features to claim 1, and are therefore patentable for at least the same reasons as claim 1. Claim 118 depends from and adds features to claim 117, and is therefore patentable for at least the same reasons as claim 117.

***VIII. Conclusion***

For the above reasons, claims 1-2, 9-10, 16, 21, 29-32, 34, 37, 41, 51-53, 56, 74, 96, 113-114, and 116-130 are patentable over the cited references. Appellants respectfully request that the Board reverse the Examiner's final rejection of these claims under 35 U.S.C. §103 and remand the present application to the Examiner for further action consistent with such determination.

Respectfully submitted,

STERNE, KESSLER



*for*

Kevin W. McCabe  
Registration No. 28,458

Attorney for Appellants

Date: April 26, 2010

***IX. CLAIMS APPENDIX (37 C.F.R. § 41.37 (c)(1)(viii))***

***Listing of Claims on Appeal:***

1. A heart valve device for connection to a first mass comprising:

a gasket body comprising an annular wall defining a gasket radius around a longitudinal axis central to the gasket body, the wall defining first and second edges, the gasket body further comprising a sewing ring including a skirt extending radially outwardly from the first edge and a complementary attachment device in the sewing ring, and

an elongate attachment device comprising one or more digitations, detents, or pawls located at an intermediate location between opposite ends of the elongate attachment device, the elongate attachment device having sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site,

wherein the complementary attachment device comprises an inner attachment radius and an outer attachment radius,

wherein the gasket radius, the inner attachment radius and the outer attachment radius are measured from the longitudinal axis, and wherein the outer attachment radius is greater than the gasket radius, and

wherein the complementary attachment device comprises a receptacle, the receptacle comprising a ratchet tooth for self-ratchetedly engaging the one or more digitations, detents, or pawls on the elongate attachment device received therethrough.

2. The device of Claim 1, wherein the inner attachment radius is greater than the gasket radius.

9. The device of Claim 1, wherein the complementary attachment device is resilient.

10. The device of Claim 1, wherein the complementary attachment device is deformable.

16. The device of Claim 1, wherein the complementary attachment device comprises an internal obstacle.

21. The device of Claim 1, wherein the sewing ring comprises a fabric.

29. The device of Claim 1, wherein the receptacle comprises a can.

30. The device of Claim 29, wherein the can is deformable.

31. The device of Claim 29, wherein the can is resilient.

32. A heart valve device for connection to a first mass comprising:

a gasket body comprising an annular wall defining a gasket radius around a longitudinal axis central to the gasket body, the wall defining first and second edges, the gasket body further comprising a sewing ring including a skirt extending radially outwardly from the first edge and a complementary attachment device, and

an elongate attachment device comprising a plurality of digitations, detents, or pawls located at an intermediate location between opposite ends of the elongate attachment device, the elongate attachment device having sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site,

wherein the complementary attachment device comprises an inner attachment radius and an outer attachment radius,

wherein the gasket radius, the inner attachment radius and the outer attachment radius arc measured from the longitudinal axis, and wherein the outer attachment radius is greater than the gasket radius, and

wherein the complementary attachment device further comprises a can and the can is fixedly attached to the gasket body, the can comprising a ratchet tooth for self-ratchetedly engaging the digitations, detents, or pawls on the elongate attachment device when the elongate attachment device is received through the can.

34. The device of Claim 29, wherein the can comprises solid walls.

37. A heart valve device for connection to a first mass comprising:

a gasket body comprising an annular wall defining a gasket radius around a longitudinal axis central to the gasket body, the wall defining first and second edges, the gasket body further comprising a sewing ring including a skirt extending radially outwardly from the first edge and a complementary attachment device, and

an elongate attachment device comprising a plurality of digitations, detents, or pawls located at an intermediate location between opposite ends of the elongate attachment device, the elongate attachment device having sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site,

wherein the complementary attachment device comprises an inner attachment radius and an outer attachment radius,

wherein the gasket radius, the inner attachment radius and the outer attachment radius are measured from the longitudinal axis, and wherein the outer attachment radius is greater than the gasket radius, and

wherein the complementary attachment device further comprises a can and the can comprises a plurality of ratchet teeth for self-ratchetedly engaging the digitations, detents, or pawls on the elongate attachment device when the elongate attachment device is received through the can.

41. The device of Claim 1, wherein the complementary attachment device is integral with the gasket body.

51. The device of Claim 1, further comprising a mechanical valve attached to the gasket body.

52. The device of Claim 1, further comprising a biological valve attached to the gasket body.

53. The device of Claim 1, further comprising a leaflet attached to the gasket body.

56. The device of Claim 1 [[54]], wherein the attachment device comprises a suture.

74. A heart valve device for connection to a first mass comprising:

a gasket body comprising an annular wall covered by fabric,

a leaflet attached to the gasket body,

an elongate attachment device comprising a plurality of digitations, detents, or pawls located at an intermediate location between opposite ends of the elongate attachment device, the elongate attachment device having sufficient length such that the gasket body can be parachuted down the elongate attachment device to an implantation site, and

a discrete receptacle attached to the gasket body for receiving the elongate attachment device therethrough, the receptacle comprising teeth elements comprising shelves and slopes for self-fixturingly ratcheting the attachment device through the receptacle.

96. A heart valve device for connection to a first mass, comprising:

an annular body comprising a wall defining a circumference;

a plurality of receptacles spaced apart around the circumference of the wall, each receptacle comprising an element defining a shelf and a slope; and

a plurality of elongate attachment devices receivable through the receptacles, each attachment device comprising a detent for self-fixturingly ratcheting through a respective receptacle, the elongate attachment devices having sufficient length such that the annular body can be parachuted down the elongate attachment devices to an implantation site;

wherein each attachment device comprises a plurality of detents spaced apart along a length of the attachment device at an intermediate location between opposite ends of the respective attachment device.

113. A heart valve assembly for implantation within a biological annulus, comprising:

a heart valve assembly comprising a crown carrying leaflets;

a gasket body comprising an annular wall and a sewing ring attached to the annular wall, the sewing ring comprising a skirt extending radially outwardly from an edge of the wall;

a plurality of fixturing devices for attaching the gasket body to the biological annulus;  
and

a plurality of elongate attachment devices receivable through respective fixturing devices and having sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site,

wherein each attachment device comprises a plurality of detents spaced apart along a length of the attachment device at an intermediate location between opposite ends of the respective attachment device.

114. The heart valve assembly of claim 113, wherein each detent comprises an angled tab.

116. A heart valve assembly for implantation within a biological annulus, comprising:

a heart valve assembly comprising a crown carrying leaflets;

a gasket body comprising an annular wall and a sewing ring attached to the annular wall, the sewing ring comprising a skirt extending radially outwardly from an edge of the wall;

a plurality of fixturing devices for attaching the gasket body to the biological annulus;  
and

a plurality of elongate attachment devices receivable through respective fixturing devices,

the elongate attachment devices having sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site,

wherein each fixturing device comprises an element defining a shelf and a slope located at an intermediate location between opposite ends of the respective attachment device, the fixturing devices configured for receiving respective elongate attachment devices therethrough, each attachment device comprising a detent for self-fixturingly ratcheting through a respective fixturing device; and

wherein each fixturing device comprises teeth elements for engaging the detent on the respective attachment device.

117. A heart valve assembly for implantation within a biological annulus, comprising:

a heart valve assembly comprising a crown carrying leaflets;

a gasket body comprising an annular wall and a sewing ring attached to the annular wall, the sewing ring comprising a skirt extending radially outwardly from an edge of the wall;

a plurality of fixturing devices for attaching the gasket body to the biological annulus; and a plurality of elongate attachment devices receivable through respective fixturing devices, the elongate attachment devices having sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site,

wherein each fixturing device comprises an element defining a shelf and a slope, the fixturing devices configured for receiving respective elongate attachment devices therethrough, each attachment device comprising a detent located at an intermediate location between opposite ends of the respective attachment device for self-fixturingly ratcheting through a respective fixturing device; and

wherein each fixturing device comprises a plurality of shelves and slopes.

118. The heart valve assembly of claim 117, wherein each attachment device comprises a plurality of detents spaced apart along a length of the attachment device.

119. A heart valve device for connection to a first mass, comprising:

an annular body comprising a wall defining a circumference;

a plurality of receptacles spaced apart around the circumference of the wall, each receptacle comprising an element defining a shelf and a slope; and

a plurality of elongate attachment devices receivable through the receptacles and having sufficient length such that the annular body can be parachuted down the elongate attachment devices to an implantation site, each elongate attachment device comprising a plurality of digitations, detents, or pawls at an intermediate location between opposite ends of

the respective attachment device for self-fixturingly ratcheting through a respective receptacle.

120. The device of claim 119, further comprising leaflets attached to the annular body.

121. The device of claim 119, wherein the attachment devices comprise sutures.

122. The device of claim 119, wherein the attachment devices comprise filaments.

123. The device of claim 119, wherein the plurality of digitations, detents, or pawls are fixedly attached to the elongate attachment device.

124. The device of claim 119, wherein the element comprises teeth internal to the receptacles.

125. A heart valve assembly for implantation within a biological annulus, comprising:

a heart valve assembly comprising a crown carrying leaflets;

a gasket body comprising an annular wall and a sewing ring attached to the annular wall, the sewing ring comprising a skirt extending radially outwardly from an edge of the wall;

a plurality of fixturing devices on the gasket body for attaching the gasket body to the biological annulus; and

a plurality of elongate attachment devices receivable through respective fixturing devices and having sufficient length such that the gasket body can be parachuted down the elongate attachment devices to an implantation site, each elongate attachment device comprising a plurality of digitations, detents, or pawls at an intermediate location between opposite ends of the respective attachment device for self-fixturingly ratcheting through a respective fixturing device.

126. The heart valve assembly of claim 125, wherein the plurality of fixturing devices comprise a plurality of receptacles spaced apart around the circumference of the wall, each receptacle comprising an element defining a shelf and a slope, the receptacles configured for receiving respective elongate attachment devices therethrough.

127. The heart valve assembly of claim 126, wherein the element comprises teeth internal to the receptacles.

128. The heart valve assembly of claim 125, wherein the attachment devices comprise sutures.

129. The heart valve assembly of claim 125, wherein the attachment devices comprise filaments.

130. The heart valve assembly of claim 125, wherein the plurality of digitations, detents, or pawls are fixedly attached to the elongate attachment device.

***X. EVIDENCE APPENDIX (37 C.F.R. § 41.37 (c)(1)(ix))***

Copies of the evidence relied upon by Appellants in this Appeal Brief are provided.

The Table below sets forth the location of the evidence in the Record:

<b>Exhibit</b>	<b>Title of Exhibit</b>	<b>Location in the Record</b>
Exhibit 1	U.S. Patent No. 6,241,765	First cited by the Examiner in the Office Action mailed August 2, 2006
Exhibit 2	U.S. Patent No. 4,548,202	First cited by the Examiner in the Office Action mailed August 19, 2008
Exhibit 3	U.S. Patent No. 6,589,279	First cited by the Examiner in the Office Action mailed July 24, 2009
Exhibit 4	U.S. Patent No. 6,066,160	First cited by the Examiner in the Office Action mailed July 19, 2007

Thomas J. FOGARTY, et al.  
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***XI. RELATED PROCEEDINGS APPENDIX (37 C.F.R. § 41.37 (c)(1)(x))***

None.